February 16, 2018

Cook Incorporated
Samuel Engelman
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K171600
Trade/Device Name: Renal Access Cobra Catheter, Kumpe Access Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: KOD
Dated: January 10, 2018
Received: January 11, 2018

Dear Samuel Engelman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)*

K171600

Device Name
Renal Access Cobra Catheter

Indications for Use *(Describe)*
This device is intended for delivery of contrast media as well as access, advancement, or exchange of wire guides in the renal area.

Type of Use *(Select one or both, as applicable)*

✓ Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda. hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)*

K171600

Device Name
Kumpe Access Catheter

Indications for Use *(Describe)*
These devices are intended for access and catheterization of the urinary tract, including the following applications:

- Delivery of contrast media
- Navigation of a tortuous ureter
- Access, advancement, or exchange of wire guides

Type of Use *(Select one or both, as applicable)*

✓ Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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**2.0 510(k) Summary**

**Renal Access Cobra Catheter and Kumpe Access Catheter**
**21 CFR §807.92**
**Date Prepared: May 31, 2017**

**Submitted By:**

| | |
|---|---|
| Submission: | Traditional 510(k) Premarket Notification |
| Applicant: | Cook Incorporated |
| Contact: | Samuel Engelman |
| Applicant Address: | Cook Incorporated<br>750 Daniels Way<br>Bloomington, IN 47404 |
| Contact Phone: | (812) 335-3575 x104340 |
| Contact Fax: | (812) 332-0281 |

**Device Information:**

| | |
|---|---|
| Trade Name: | Renal Access Cobra Catheter<br>Kumpe Access Catheter |
| Common Name: | Urological Catheter |
| Classification Name: | Urological Catheter and Accessories |
| Classification Regulation: | 21 CFR §876.5130, Product Code KOD |
| Device Class/Classification Panel: | Class II, Gastroenterology/Urology |

**Predicate Device:**

Imager™ II Catheter (K102527)

**Subject Device Descriptions:**

The Renal Access Cobra Catheter is used in the delivery of contrast media as well as access, advancement, or exchange of wire guides in the renal area. The catheter consists of tubing with a proximal connector cap and a winged female Luer lock adapter. The catheter has a total length of 65 cm and an outer diameter of 6.0 French. The catheter tubing is composed of a polymer reinforced with braided wire. The distal end of the catheter has a hook shaped curve. The tubing French size and compatible wire guide size are printed on one side of the winged female Luer lock adapter; on the other side is the name of the manufacturer.

The Kumpe Access Catheter is used in the urinary tract for the delivery of contrast media, navigation of a tortuous ureter, and access, advance, or exchange of wire guides. The

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catheter consists of tubing with a proximal cap and female Luer lock adapter. The catheter has a total length of 65 cm and an outer diameter of 5.0 French. The catheter tubing is composed of a polymer reinforced with braided wire. The distal tubing configuration is angled at approximately 45 degrees. The tubing French size, compatible wire guide size, and manufacturer are printed on the cap.

**Indications for Use:**

*Renal Access Cobra Catheter*
This device is intended for delivery of contrast media as well as access, advancement, or exchange of wire guides in the renal area.

*Kumpe Access Catheter*
These devices are intended for access and catheterization of the urinary tract, including the following applications:

- Delivery of contrast media
- Navigation of a tortuous ureter
- Access, advancement, or exchange of wire guides

**Comparison to Predicate Device:**

The subject devices have similar indications for use, methods of operation, and fundamental technological characteristics as the predicate device. Differences between the subject devices and the predicate device include a difference in indications, dimensional variations, and materials. Characteristics of the subject devices that differ from the predicate device are supported by testing and analysis.

**Substantial Equivalence Table**

| | PREDICATE DEVICE | SUBJECT DEVICE | SUBJECT DEVICE |
|---|---|---|---|
| | **Imager ™ II Catheter** | **Renal Access Cobra Catheter** | **Kumpe Access Catheter** |
| **510(k) Number** | K102527 | Subject of Submission | Subject of Submission |
| **Manufacturer** | Boston Scientific | Cook Incorporated | Cook Incorporated |
| **Regulation Number** | 21 CFR §876.5130 | Identical | Identical |
| **Product Code** | KOD | Identical | Identical |
| **Classification Name** | Urological Catheter | Identical | Identical |
| **Device Class** | Class II | Identical | Identical |

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**Substantial Equivalence Table – Continued**

| | PREDICATE DEVICE | SUBJECT DEVICE | SUBJECT DEVICE |
|---|---|---|---|
| | **Imager ™ II Catheter** | **Renal Access Cobra Catheter** | **Kumpe Access Catheter** |
| **Indications for Use** | The Imager™ II Urology Torque Catheter is indicated for use in facilitating access to the urinary tract, either through a retrograde or antegrade route, and may be used in conjunction with a guidewire or for the infusion of radiopaque contrast material. The Imager™ II Urology Torque Catheter is also indicated for the infusion of gels, such as BackStop™, intended for use in the urinary tract. | This device is intended for delivery of contrast media as well as access, advancement, or exchange of wire guides in the renal area. | These devices are intended for access and catheterization of the urinary tract, including the following applications:<br>• Delivery of contrast media<br>• Navigation of a tortuous ureter<br>• Access, advancement, or exchange of wire guides |
| **Sterilization** | Unknown | Ethylene Oxide | Ethylene Oxide |
| **Single Use Device** | Yes | Identical | Identical |
| **Packaging** | Unknown | Tyvek-Polyethylene peel-open pouch | Tyvek-Polyethylene peel-open pouch |
| **Shelf Life** | Unknown | 3 Years | 3 Years |
| **Catheter Specifications** | | | |
| **Distal Tubing Design** | Straight, Angled, Hook | Hook | Angled |
| **Radiopacity** | Radiopaque | Identical | Identical |
| **Proximal Adapter** | Luer Lock Hub | Identical | Identical |
| **Catheter Dimensions** | | | |
| **Catheter Diameter (Fr)** | 5.0 | 6.0 | 5.0 |
| **Catheter Length (cm)** | 40, 65, 100 | 65 | 65 |
| **Catheter Materials** | | | |
| **Tubing** | Polymer Reinforced with Stainless Steel Braided Wire | Identical | Identical |

Differences between the characteristics of the subject device sets and the predicate devices are supported by testing.

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**Performance Data:**

The following testing was performed in order to demonstrate that the proposed Renal Access Cobra Catheter and Kumpe Access Catheter met applicable design and performance requirements.

- Dimensional and Compatibility Testing
- Radiopacity Testing
- Kink Radius Testing
- Blockage and Leakage Testing
- Tensile Testing
- Biocompatibility Testing
- Environmental Testing
- Sterilization Testing
- Accelerated Age Testing

**Conclusion:**

The results of these tests support a conclusion that the Renal Access Cobra Catheter and Kumpe Access Catheter will perform as intended. The subject devices do not raise new questions of safety or effectiveness as compared to the predicate device.